

REMARKS

Disposition of Claims

Claims 1-23 are pending in this application. Claims 1, 10 and 18 are independent. The remaining claims depend, directly or indirectly, from claims 1, 10 and 18.

Claims 1, 10, and 18 have been amended in this reply to include the limitations discussed during the telephone conference of July 8, 2004. These limitations include the clarification of the location of the wedge, disclaiming the area under the center of a first metatarsal, the clarification of the concept of deflection of the proximal phalanx, and the clarification of the direction of inclination. The amendments also clarify that the wedge will be properly sized and placed, so that there is no ambiguity as to the location or position of the wedge, regardless of foot size. No new matter has been added by way of these amendments. Support for these amendments may be found at least in Figure 14 of the application as filed.

Furthermore, in consideration of the Examiner's assertions that functional claim language and statements of intended use do not make an otherwise unpatentable claim patentable, Applicant submits that the language introduced into claims 1 and 18 by way of these amendments imparts structural limitations to the claimed embodiments. Such language, showing the interrelationship of parts of an invention, has been upheld by the courts to be acceptable for differentiating a claimed invention over the prior art. *See e.g.*, *In re Venezia*, 530 F.2d 956 (C.C.P.A. 1976) (language such as "adapted to be positioned," "adapted to be affixed," and "adapted to be fitted over" is acceptable when it precisely defines present structural attributes of interrelated parts); and, *Dennison Mfg. Co. v. Ben Clements and Sons, Inc.*, 467 F.Supp. 391 (S.D.N.Y. 1979) ("adapted to" language is acceptable when it excludes a particular interpretation from the scope of the claims, when read in light of the specification and drawings).

With respect to the negative limitations of amended claims 1, 10, and 18, as stated in the M.P.E.P. at § 2173.05(i), as long as the claim complies with 35 U.S.C. § 112, there

is nothing inherently ambiguous or uncertain about a negative limitation. Accordingly, the limitation that the wedge will not extend under a first metatarsal is believed by the Applicant to be proper, and to clearly differentiate the claimed embodiments over the cited prior art.

Examiner Interview

A telephone conference was held on July 8, 2004, between the Applicant, Applicant's attorney, and Examiner Mohandes. During the interview, differences between the instant application and the prior art were discussed. The Examiner indicated that further clarification to the claims was required, specifically with respect to the length of the claimed apparatus and the direction of inclination provided by the claimed apparatus. In light of these discussions, the instant claims have been amended accordingly, and Applicant believes the application is now in condition for allowance.

Rejections under 35 U.S.C § 102

Claims 1-3 and 6 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,092,314, issued to Rothbart ("Rothbart"). Claim 1 has been amended in this response per the Examiner's suggestion to clarify the metes and bounds of the claimed embodiment. To the extent the rejection may apply to the amended claims, it is respectfully traversed.

Amended claim 1 recites an orthopedic appliance comprising a wedge for placement beneath a toe and *not extending under the center of a first metatarsal*, and having a top surface adapted to support the toe and a bottom surface, wherein an angle of inclination *in the proximal to distal direction* between the top surface and the bottom surface of the wedge is between 1 and 60 degrees *and deflects a proximal phalanx upwardly, relative to the first metatarsal.*

In contrast to such a configuration, Rothbart discloses a forefoot support surface having a back edge positioned **posterior to the first metatarsal (36) but anterior to a plantar surface of the calcaneus (27)** (Col. 6, ll. 30-32, and Figure 6, shown with annotations below). Furthermore, the apparatus according to Rothbart is inclined *across* the medial column of the foot, and not in a proximal to distal direction, as required by amended claim 1 (a proximal to distal inclination occurs *along* the medial column of the foot).

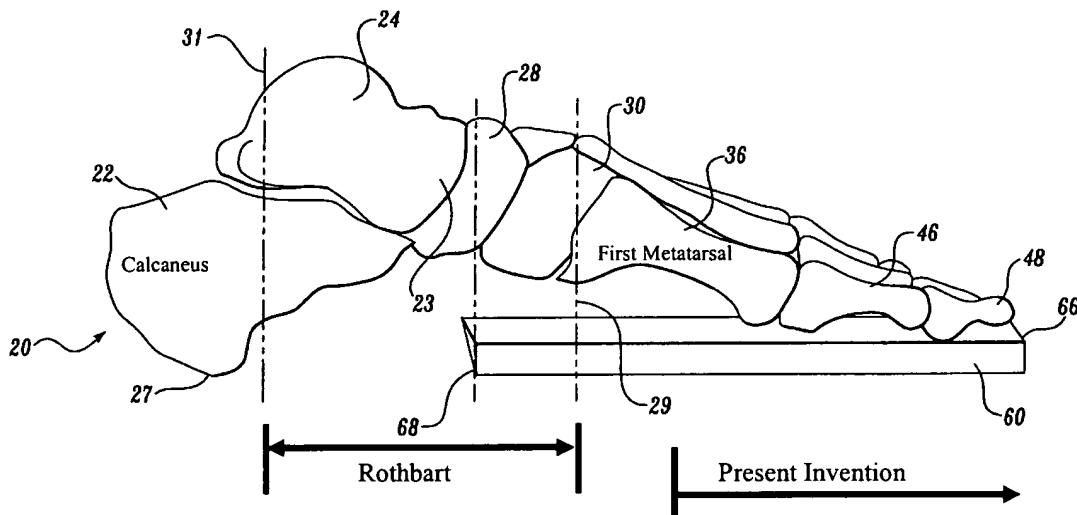


Figure 6 of Rothbart (annotated)

As shown in Figure 6, and described at Col. 6, ll. 33-37, "the back edge 68 may lie in, along or between a reference line 29 at the posterior end of the first metatarsal 36 to a reference line 31 at the anterior end of the plantar surface 27 of the calcaneus 22." Thus Rothbart is *clearly disclaiming* the location of a wedge according to claim 1 of the instant application, which will not extend beneath the center of the first metatarsal (36). The

Rothbart device clearly lies beneath the center of the first metatarsal *in every embodiment disclosed.*

In contrast to Rothbart, the invention embodied in claim 1 deflects a proximal phalanx upwardly with respect to a first metatarsal, thereby advantageously facilitating plantarflexion of the first metatarsal through the late midstance and propulsive phases of gait (Paragraph 66 of the current application). The invention according to Rothbart instead elevates the first metatarsal and does not facilitate the biomechanical action (described above) that is an advantage of the instant invention.

In view of the above Rothbart fails to show or suggest the present invention as recited in amended claim 1. Thus, claim 1 is patentable over Rothbart. Dependent claims 2-3 and 6 are allowable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1, 5, and 10-11 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,333,472, issued to Tager (“Tager”). Claims 1 and 10 have been amended in this response per the Examiner’s suggestion to clarify the metes and bounds of the claimed embodiments. Specifically, claims 1 and 10 have been amended to recite that the claimed apparatus deflects the proximal phalanx upwardly relative to the first metatarsal, *in a proximal to distal direction.* To the extent that this rejection may apply to the amended claims, it is respectfully traversed.

Tager discloses a series of differentially-sized geometrically-shaped prosthetic devices to be disposed in footwear. These devices may be situated underneath a region extending from the calcaneum bone of the rear foot (See Fig. 7 and Col. 4, ll. 9-14) to the first metatarsal/first phalanx region (See Fig. 9 and Col. 4, ll. 35-37). However, Tager fails to suggest or disclose an upwardly deflection of a proximal phalanx relative to a first metatarsal, occurring in a proximal to distal direction, as required by the amended claims.

For at least this reason, amended claims 1 and 10 are patentable over Tager. Claims 5 and 11, which depend from claims 1 and 10, respectively, are similarly patentable. Accordingly, withdrawal of this rejection is respectfully requested.

Rejections under U.S.C. § 103

Claims 4-5 stand rejected under 35 U.S.C. § 103 as being obvious over Rothbart. Claims 4-5 depend from amended claim 1. To the extent that this rejection may still apply to the amended claims, it is respectfully traversed.

As previously discussed, the amendments to claim 1 include the clarification of the wedge's location, specifically, that the wedge does not extend under the center of a first metatarsal, and that the upwardly deflection of the proximal phalanx relative to the first metatarsal occurs in a proximal to distal direction. Because Rothbart fails to show or suggest either of these claimed limitations, claim 1 is patentable over Rothbart. Claims 4 and 5, which depend from claim 1, are patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 7-9 stand rejected under 35 U.S.C. § 103 as being obvious over Rothbart in view of either Brock '927 or Jacoby '046. Claims 7-9 depend from amended claim 1. To the extent that this rejection applies to the amended claims, it is respectfully traversed.

As previously discussed, Rothbart neither discloses nor suggests an apparatus that does not extend under the center of a first metatarsal. Furthermore, the apparatus according to Rothbart does not deflect a proximal phalanx upwardly relative to a first metatarsal.

Neither Brock '927 nor Jacoby '046 discloses or suggests that which Rothbart fails to teach, specifically a wedge that does not extend under the center of a first metatarsal and/or a deflection of a proximal phalanx relative to a first metatarsal. Therefore, amended claim 1 is patentable over this combination of references. Dependent claims 7-9 are similarly patentable. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 7-9, and 15-23 stand rejected under 35 U.S.C. § 103 as being obvious over Tager or Rothbart (both references are cited in the rejection, although only Tager is discussed) in view of either Brock '927 or Jacoby '046. These rejections are respectfully traversed.

As previously discussed, there is absolutely no disclosure or suggestion in Rothbart or Tager of a wedge that does not extend beneath the center of a first metatarsal and that deflects a proximal phalanx upwardly relative to a first metatarsal, as required by independent claims 1, 10 and 18. Furthermore, neither Brock '927 nor Jacoby '046 discloses or suggests that which Rothbart and Tager fail to teach.

Accordingly, amended claims 1, 10, and 18 are patentable over this combination of references. Claims 7-9 and 15-23, which depend from amended claims 1, 10 and 18, are similarly patentable. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 10-14 stand rejected under 35 U.S.C. § 103 as being obvious over Rothbart in view of Tager. Independent claim 10 has been amended in this response to clarify that the claimed embodiment does not extend under a first metatarsal, and that the claimed

apparatus will deflect a primary phalanx upwardly relative to a first metatarsal, in a proximal to distal direction. To the extent that this rejection may apply to the amended claims, it is respectfully traversed.

As previously discussed, neither Rothbart nor Tager discloses or suggests a wedge that does not extend beneath the center of a first metatarsal and that deflects a proximal phalanx upwardly relative to a first metatarsal, as required by independent claims 1, 10 and 18. Therefore, amended claim 10 is patentable over this combination of references. Claims 11-14, which depend from amended claim 10, are similarly patentable. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

The Applicant believes this paper to be responsive to every issue raised by the Examiner in the Office Action dated May 24, 2004. If this belief is incorrect, or other issues arise, please do not hesitate to contact the undersigned or his associates at the telephone number listed below. This application is now considered to be in condition for allowance and favorable action in the form of a Notice of Allowance is respectfully requested. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 09166/002001).

Respectfully submitted,

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